

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of: **David S. Garvey and Inigo Saenz de Tejada**

U.S. Application No.: **Not Yet Assigned**

Filing Date: **December 21, 2001**

Entitled: **Nitrosated and Nitrosylated Phosphodiesterase Inhibitor Compounds,  
Compositions and Their Uses**

Attorney Docket No: **102258.326 US2**

**ATTN: BOX PATENT APPLICATION**

Assistant Commissioner for Patents  
Washington, DC 20231

**PRELIMINARY AMENDMENT**

Prior to consideration of the above application on the merits, please enter the following amendment without prejudice.

**IN THE CLAIMS:**

Attached hereto as Appendix 1 is a copy of the pending claims. Attached hereto as Appendix 2 is a copy of the amendments made to the claims.

**Remarks**

After entry of the preliminary amendment, claims 8-10 are pending in the application.

Claims 1-7 have been canceled, without prejudice.

Added claim 8 is identical to claim 1 of U.S. Patent No. 6,165,975, issued on December 26, 2000. Pursuant to 37 CFR § 1.606 and § 1.607, Applicants request that an interference be declared with U.S. Patent No. 6,165,975.

Added claim 9 is identical to claim 1 of U.S. Patent No. 6,306,841, issued on October 23, 2001. Pursuant to 37 CFR § 1.606 and § 1.607, Applicants request that an interference be declared with U.S. Patent No. 6,306,841.

[illegible]

No issues of new matter should arise and entry of the amendment is respectfully requested.

Respectfully submitted,  
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Date: December 21, 2001

WASHINGTON 160077v1

## Appendix 1 – Pending Claims

8. (New) A method of treatment, in an organism, of a vascular condition, comprising administration of at least one agent at a level which enhances NO and which does not appreciably alter normal systemic vascular tone in said organism.

9. (New) A method for treating sexual dysfunction in a female individual, comprising administering to the vagina, vulvar area and/or urethra of the individual a pharmaceutical formulation that comprises an effective amount of a nitrovasodilator selected from the group consisting of sodium nitroprusside, diazenium diolates, molsidomine, linsidomine chlorohydrate, S-nitrosothiols, organic nitrates, pharmacologically acceptable salts, esters, analogs, derivatives, prodrugs and inclusion complexes of any of the foregoing, and combinations thereof.

10. (New) A method of enhancing sexuality in a female having a clitoris comprising the step of topically administering to a surface of the clitoris a composition whose primary agent is a vasodilator and whose secondary agent is a carrier in which the vasodilator is dispersed to deliver it directly to said surface so that it is retained and absorbed thereby, said composition being in a formulation and in a dosage which is substantially free of toxicity and therefore does not give rise to an adverse reaction.

## Appendix 2 – Amendments to Claims

Cancel claims 1-7, without prejudice.

8. (New) A method of treatment, in an organism, of a vascular condition, comprising administration of at least one agent at a level which enhances NO and which does not appreciably alter normal systemic vascular tone in said organism.

9. (New) A method for treating sexual dysfunction in a female individual, comprising administering to the vagina, vulvar area and/or urethra of the individual a pharmaceutical formulation that comprises an effective amount of a nitrovasodilator selected from the group consisting of sodium nitroprusside, diazenium diolates, molsidomine, linsidomine chlorohydrate, S-nitrosothiols, organic nitrates, pharmacologically acceptable salts, esters, analogs, derivatives, prodrugs and inclusion complexes of any of the foregoing, and combinations thereof.

10. (New) A method of enhancing sexuality in a female having a clitoris comprising the step of topically administering to a surface of the clitoris a composition whose primary agent is a vasodilator and whose secondary agent is a carrier in which the vasodilator is dispersed to deliver it directly to said surface so that it is retained and absorbed thereby, said composition being in a formulation and in a dosage which is substantially free of toxicity and therefore does not give rise to an adverse reaction.